MAY - 8 2012

K120394
Page 1 of 3

## II. 510(k) SUMMARY

| | |
|---|---|
| Applicant: | Ansell Healthcare Products, LLC<br>1635 Industrial Road<br>Dothan, AL 36303<br>USA<br>Phone: (334) 615-2563<br>Fax: (334) 615-2574 |
| Contact Person: | Cynthia Ingram, Regulatory Affairs Manager, Americas |
| Date Prepared: | February 02, 2012 |
| Proprietary Name: | LifeStyles® Zero® Lubricated Latex Condom |
| Common Name: | Latex Condom |
| Classification Name: | Condom (21 CFR 884.5300; Product Code HIS) |
| Predicate Device(s): | Billy Boy Male Latex Condoms (K103119) |

Device Description:
This condom is made of a natural rubber latex sheath, which completely covers the penis with a closely fitted membrane. The device is a straight-walled, cylindrical, lubricated condom with a reservoir tip. The device is designed to conform to the specifications of ASTM D3492, *Standard Specification for Rubber Contraceptives (Male Condoms)* and is provided in a foil package.

Intendications for Use:
This latex condom has the same intended use as the predicate condom. LifeStyles® Zero® condom is used for contraceptive and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

Technological Characteristics:
Both this condom and the predicate device identified above are made from natural rubber latex, with designs that are biocompatible and in conformance with the requirements of the ASTM D 3492-08 condom standard. Both are straight-walled, cylindrical, lubricated condoms, with a reservoir tip, provided in a foil package. This condom is unscented and the predicate device is scented. The absence of scent has no material impact on safety and effectiveness.

The table below compares specific technological characteristics of the condom to the predicate:

**II. 510(k) SUMMARY, Continued**

| | LifeStyles® Zero® Lubricated Latex Condom | Billy Boy Male Latex Condoms |
|---|---|---|
| Material | Natural rubber latex | Natural rubber latex |
| Condom Film | Compounded natural rubber latex formulation | Compounded natural rubber latex formulation |
| Design | Straight-walled, cylindrical, reservoir tip | Straight-walled, cylindrical, reservoir tip |
| Lubricant | Silicone (silicone oil) | Silicone (silicone oil) |
| Primary Package | Foil | Foil |
| Length | 185 mm | 185 mm |
| Width | 51 mm | 52 mm |
| Thickness | 0.04 mm | 0.04 to 0.08 mm |
| Color | Natural | Natural |
| Scented | No | Yes |

Summary:
This condom has the same intended use and basic technological characteristics as the predicate device. This condom is as safe and effective as the predicate device.

**II. 510(k) SUMMARY, Continued**

| | LifeStyles® Zero® Lubricated Latex Condom | Billy Boy Male Latex Condoms |
|---|---|---|
| Material | Natural rubber latex | Natural rubber latex |
| Condom Film | Compounded natural rubber latex formulation | Compounded natural rubber latex formulation |
| Design | Straight-walled, cylindrical, reservoir tip | Straight-walled, cylindrical, reservoir tip |
| Lubricant | Silicone (silicone oil) | Silicone (silicone oil) |
| Primary Package | Foil | Foil |
| Length | 185 mm | 185 mm |
| Width | 51 mm | 52 mm |
| Thickness | 0.04 mm | 0.04 to 0.08 mm |
| Color | Natural | Natural |
| Scented | No | Yes |

Summary:
This condom has the same intended use and basic technological characteristics as the predicate device. This condom is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ansell Healthcare Products, LLC
% Ms. Donna Di Gangi
Principal
DiGangi Consulting
4 Los Verdes Drive
SAN LUIS OBISPO CA 93401

MAY - 8 2012

Re: K120394
Trade/Device Name: LifeStyles® Zero® Lubricated Latex Condom
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: HIS
Dated: February 2, 2012
Received: February 8, 2012

Dear Ms. Gangi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K120394

Device Name: LifeStyles® Zero® Lubricated Latex Condom

Indications for Use: The LifeStyles® Zero® condom is used for contraception and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted diseases).

| | | |
|---|---|---|
| Prescription Use _____<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use __X__<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120394